UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON DERIVATIVE LITIGATION	Civil Action No. 10-2033 (FLW)
IN RE JOHNSON & JOHNSON FCPA SHAREHOLDER DERIVATIVE LITIGATION	Civil Action No. 11-2511 (FLW)
COPELAND v. PRINCE, *et al.*	Civil Action No. 11-4993 (FLW)

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY APPROVAL OF DERIVATIVE ACTION SETTLEMENT

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Plaintiffs and their Lead Counsel respectfully submit this memorandum of law in support of the Motion for Preliminary Approval of Derivative Action Settlement pursuant to Federal Rule of Civil Procedure 23.1.

I. PRELIMINARY STATEMENT

The proposed settlement of this derivative action provides substantial benefits to Johnson & Johnson ("J&J" or the "Company") and its shareholders by directly responding to and curing the governance and compliance-related deficiencies that led to J&J's significant regulatory and legal problems relating to drug marketing and medical product and device quality controls. Plaintiffs contend that the magnitude and chronic nature of J&J's ongoing problems are in large part due to the failure of J&J's senior management and J&J's board of directors (the "Board") to take responsibility for identifying and addressing problems before they spun out of control. Before this settlement, J&J's senior management and Board denied knowledge about J&J's compliance and quality control problems, largely because they implemented a de-centralized compliance and internal reporting system. As a direct result of this settlement, information about compliance or quality control issues at J&J's far-flung businesses that are not promptly cured will, as appropriate, be directed up the chain of power so that J&J's senior managers and its Board will be compelled to become informed and take effective action to cure those issues in a timely manner. By implementing an effective "bottom-up" compliance and quality control reporting structure with mandatory reporting requirements, Plaintiffs have fundamentally improved J&J's approach to these issues, and by requiring the Board and management to take ownership of regulatory and legal issues before they become major problems, Plaintiffs are providing significant value to J&J and its shareholders going forward.

For many years, J&J has prided itself on the success of its de-centralized business model. Providing *commercial* autonomy to hundreds of subsidiaries may well have been a good way to

increase revenue and profits, and is not changed by the settlement. However, Plaintiffs believe that a "de-centralized approach" to *compliance and quality control* resulted in a lack of accountability, a structural excuse for plausible deniability among senior management and J&J's Board, and ultimately, a recipe for disaster. In 2010, that disaster struck, as regulators, consumers and shareholders realized that J&J's key subsidiaries had long suffered similar problems with drug marketing and medical product quality control, yet there was no centralized management or Board that took responsibility for rectifying the problems, much less in a timely manner. Thus, for example, as alleged in the Derivative Actions (discussed below), in January, J&J subsidiary McNeil Consumer Healthcare ("McNeil") received an FDA inspection report detailing serious manufacturing deficiencies and violations of the FDA's current Good Manufacturing Practices ("cGMP") regulations at McNeil's manufacturing facility in Las Piedras, Puerto Rico. In April, the FDA discovered that the Company did not adhere to cGMP regulations at McNeil's facility in Fort Washington, Pennsylvania either, and that contaminated raw materials "were approved for use to manufacture several finished lots of Children's and Infant's Tylenol drug products, which remain within expiration date(s) on the market." The resulting recalls affected approximately 70% of all J&J products for infants and children. From August to December, J&J subsidiary Vision Care recalled almost 600,000 boxes of contact lenses around the world because they contained higher-than-expected levels of acid and were burning users.

During 2010, J&J also faced significant exposure to criminal and civil enforcement actions in connection with alleged violations of anti-kickback and drug marketing laws. In January, the U.S. Department of Justice intervened in a *qui tam* suit alleging that J&J subsidiary Ortho-McNeil-Janssen Pharmaceuticals Inc. ("Janssen") paid tens of millions of dollars in illegal

kickbacks to Omnicare – a pharmacy provider to patients in nursing homes – to increase the procurement of Risperdal (a powerful antipsychotic drug associated with an increased risk of death for elderly patients with dementia). In April, Janssen and Ortho-McNeil Pharmaceutical LLC agreed to pay $81.5 million and entered into a corporate integrity agreement with the government to resolve criminal and civil liability arising from the illegal promotion of Topamax (an anti-epileptic drug) for unapproved uses in children. In August, the FDA ordered J&J subsidiary DePuy Orthopaedics to cease sales of its Corail hip system because the Company was illegally marketing it for an unapproved use. And in October, the Louisiana Attorney General obtained a $257.7 million verdict against Janssen in connection with the illegal promotion of Risperdal in Louisiana. Other verdicts in other states soon followed.

Plaintiffs filed suit in light of the tsunami of regulatory and legal difficulties overtaking J&J. Plaintiffs believed that the J&J Board and members of senior management should be held responsible for not stopping widespread wrongdoing that had seriously harmed J&J's business and goodwill. Plaintiffs alleged that the Individual Defendants breached their fiduciary duties by disregarding numerous red flags warning them that key J&J subsidiaries were engaging in unlawful manufacturing practices and widespread violation of mandatory drug marketing laws over long periods of time. Plaintiffs were concerned that future violations of cGMP and drug marketing laws would further undermine consumer confidence in the J&J brand and result in draconian regulatory action, involving multi-billion dollar fines and possible federal debarment of one or more J&J subsidiaries, which might wipe out a substantial part of J&J's revenues and severely damage J&J shareholders.

In response, Defendants mounted a vigorous litigation defense based on what Plaintiffs believed to be an overly expansive interpretation of New Jersey Corporate law. Nevertheless,

the parties began good faith settlement discussions in the summer of 2010. Following several prior discussions, on August 31, 2011, Co-Lead Counsel for the Demand Futile Actions presented Defendants with a detailed settlement proposal. This initial proposal, which formed the foundation for the majority of the proposed settlement, included provisions for corporate governance reforms that had been reviewed and crafted, in part, by former Chairman of the Securities and Exchange Commission Harvey Pitt, and initiatives for reforms and improvements to J&J's quality control and compliance structure which reflected input from an experienced pharmaceutical executive, Dr. Mitchell Glass. Among other things, the initial proposal included a proposed charter for a new Regulatory and Compliance Committee of the Board that would ensure that the Board regularly received critical compliance and quality information from each subsidiary and could no longer deny having knowledge of compliance and quality-related issues based on J&J's decentralized operations, and proposed Product Risk Management provisions addressing the identification and remediation of all product-related issues from the ground up.

On September 29, 2011, the Court granted Defendants' motion to dismiss, but gave Demand Futility Plaintiffs leave to replead. Shortly after the issuance of the Court's opinion, Defendants informed Plaintiffs that they were willing to continue discussing the non-monetary components of the August 31 proposal. Plaintiffs determined that while litigation could, in theory, lead to an eventual post-trial money judgment, protracted litigation would not allow for timely implementation of the extensive changes to the Company's compliance and quality structure that Plaintiffs believed necessary and potentially attainable through negotiating meaningful corporate governance changes. During the course of the settlement negotiations, Lead Demand Futile Counsel consulted with Chairman Pitt about possible reforms to J&J's corporate governance structure that would help ensure Board awareness of, and accountability

for continued compliance violations. Lead Demand Futile Counsel also consulted with Dr. Glass about possible reforms to J&J's management system for identifying, reporting and addressing noncompliance with cGMP regulations and drug marketing laws.

As set forth below, the proposed settlement significantly improves the way J&J will approach compliance and quality control. The settlement requires the adoption by J&J's Board of the Quality and Compliance Core Objective, which directly addresses core issues of early identification and tracking of resolution of issues across the range of products that J&J manufactures and sells. In addition, J&J must implement a company-wide Product Risk Management ("PRM") Standard, designed to ensure that issues and problems are identified at the earliest stage, responsibility of their resolution is assigned, specific timeframes for resolution are established, performance against those timelines is monitored and tracked, and reporting and escalation occurs in a consistent manner across J&J. Critical information will no longer be confined to the level of J&J subsidiaries.

In addition, the proposed settlement ensures that the Board, through the activities of the new Regulatory, Compliance and Government Affairs Committee (the "RCGC"), will have the information necessary to exercise meaningful oversight over J&J's compliance with FDA rules and regulations by providing a Charter and detailed Operating Procedure for the Committee. Under the Charter and Operating Procedure, the members of the new RCGC must be independent directors, must receive regular reports from key J&J officers, including J&J's Chief Quality Officer ("CQO"), J&J's Chief Compliance Officer ("CCO"), and J&J's Vice President Corporate Internal Audit (V.P.CIA"), and must provide an annual report to J&J's shareholders confirming, among other things, that the Committee received reports regarding significant compliance and quality matters, and reported its findings to the full Board. The proposed

settlement thus gives the Board the necessary tools and clear responsibility to oversee J&J's enterprise-wide compliance efforts, and eliminates any ignorance defense by the Board and senior management for continued noncompliance.

Plaintiffs believe that the proposed settlement represents an outstanding achievement, of which both Plaintiffs and J&J can be proud. The benefits of the proposed settlement, including the new Quality and Compliance Core Objective, the RCGC Charter and Operating Procedure and the implementation of the new PRM Standard, could only be achieved through vigorous advocacy, with the assistance of leading experts, and in the context of a settlement. Indeed, while a post-trial jury verdict that survived appeal may have resulted in the infusion of some amount of cash to J&J years in the future, the settlement immediately imposes affirmative obligations to create new corporate governance and reporting structures that will enhance J&J's quality and compliance efforts going forward and inure to the benefit of the Company's shareholders.

The question before the Court on this Motion is discrete – whether the settlement is sufficient to warrant preliminary approval, to disseminate notice to J&J shareholders, and to schedule a time for a final approval hearing. Plaintiffs respectfully submit that the proposed settlement provides substantial benefits to the Company and its shareholders. Because the proposed settlement meets the standard for preliminary approval, the proposed Preliminary Approval Order should be entered, notifying J&J shareholders of the proposed settlement and scheduling a final approval hearing.

II. PROCEDURAL AND FACTUAL BACKGROUND

The Derivative Actions[1] are shareholder derivative actions brought for the benefit of J&J against the Individual Defendants[2] (together with J&J the "Settling Defendants"). The Derivative Actions allege that from the late 1990s until 2010, the Individual Defendants breached their fiduciary duties to the Company and its shareholders in connection with the manufacturing, production, distribution and marketing of various J&J products and devices.

A. Demand Futile Actions

From April 21 through June 24, 2010, six Demand Futile Actions were filed in this Court, alleging that the Individual Defendants violated fiduciary duties owed to the Company by, *inter alia*, failing to ensure that the Company complied with FDA-mandated cGMP, resulting in massive product recalls and the closure of manufacturing facilities, failing to prevent the illegal marketing of major J&J drugs for unapproved uses and through payment of kickbacks and bribes (the "Demand Futility Actions").[3]

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[1] The Derivative Actions include demand letters (the "Demand Letters") sent by shareholders to the Company's Board of Directors (the "Board"), actions in which Plaintiffs allege pursuant to Fed. R. Civ. P. 23.1(b)(3)(B) that it would have been futile to demand that the Board investigate and pursue litigation against the Individual Defendants (the "Demand Futile Actions"), and actions wherein Plaintiffs allege pursuant to Fed. R. Civ. P. 23.1(b)(3)(A) that the Board wrongfully refused demands that were made on the Board (the "Demand Refused Actions").

[2] The following Individual Defendants are named in the Derivative Actions: Dominic J. Caruso, Mary Sue Coleman, James G. Cullen, Robert J. Darretta, Ian E.L. Davis, Russell C. Deyo, Michael Dormer, Seth Fischer, Colleen Goggins, Alex Gorsky, Michael M.E. Johns, Ann Dibble Jordan, Arnold G. Langbo, Ralph S. Larsen, James T. Lenehan, Susan L. Lindquist, Peter Luther, Ashley McEvoy, Robert Miller, Ann M. Mulcahy, Leo F. Mullin, William D. Perez, Christine Poon, Charles O. Prince, Steven S. Reinemund, David Satcher, Henry B. Schacht, Joseph C. Scodari, Ted Torphy, Nicholas Valeriani, William C. Weldon, and Robert N. Wilson.

[3] The Demand Futile Actions are: (i) *Calamore v. Coleman, et al.*, Case No. 3:10-cv-02033- FLW-DEA, filed April 21, 2010); (ii) *Carpenters Pension Fund of West Virginia v. Weldon, et al.*, Case No. 3:10-cv-02275- FLW-DEA, filed May 5, 2010; (iii) *Feldman v. Coleman, et al.*, Case No. 3:10-cv-02386-FLW-DEA, filed May 6, 2010; (iv) *Hawaii Laborers Pension Fund v. Weldon, et al.*, Case No. 3:10-cv-02516-FLW-DEA, filed May 14, 2010; (v)

On August 17, 2010, the Court ordered the consolidation of the Demand Futile Actions under the caption *In re Johnson & Johnson Derivative Litigation*, No. 10-2033-FLW (the "Consolidated Action") and appointed the law firms of Bernstein Litowitz Berger & Grossmann LLP; Morris and Morris LLC Counselors At Law; Carella, Byrne, Cecchi, Olstein, Brody & Agnello, P.C.; and Robbins Geller Rudman & Dowd LLP as Co-Lead Counsel for the Demand Futile Actions. *See* ECF No. 65. On December 17, 2010, Plaintiffs filed a Consolidated Amended Complaint. ECF No. 94.

Defendants moved to dismiss the Demand Futile Consolidated Amended Complaint on February 21, 2011. ECF No. 105. Following extensive briefing and oral argument on July 28, 2011, by Order dated September 29, 2011, the Court granted Defendants' motion to dismiss without prejudice. ECF Nos. 170 and 171. The time for the Demand Futile Plaintiffs to determine whether they intend to file an amended complaint, pursue a demand for production of books and records or take any other action has been extended by the Court while the parties engaged in the negotiations leading to settlement.

On May 2, 2011 and May 10, 2011, two additional demand futile actions were filed in the Court, alleging that the Individual Defendants violated the fiduciary duties they owed to the Company in connection with the Company's compliance with the Foreign Corrupt Practices Act (the "FCPA Actions"). The Court consolidated the FCPA Actions under Case No. 11-2511. [4] Following the Defendants' filing of a motion to dismiss, the parties agreed to defer further

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Ryan v. Weldon, et al., Case No. 3:10-cv-03147-FLW-DEA, filed June 18, 2010; and (vi) *Minneapolis Firefighters' Relief Association v. Weldon et al.*, Case No. 3:10-cv-03215-FLW-DEA, filed June 24, 2010.

[4] Those actions were: *Wollman v. Coleman et al.*, No. 11-02511-FLW and *Cafaro v. Coleman et al.*, No. 11- 2652-FLW. The Court consolidated those cases under Case No. 11-2511. Co-Lead Counsel in the Consolidated Action, Robbins Geller Rudman & Dowd LLP, is plaintiffs' counsel in Case No. 11-2511.

proceedings pending the negotiations leading to the proposed settlement. Other Demand Futile actions were filed in the Superior Court of New Jersey.[5] These actions have been either voluntarily stayed or stayed as duplicative of the prior-filed federal actions.

B. Demand Letters and Demand Refused Actions

From February through November 2010, a number of Demand Letters were submitted to the Board of Directors of J&J (the "Board"), demanding that the Board investigate various matters including, *inter alia*, illegal marketing of J&J drugs for unapproved uses and through payment of kickbacks and bribes, lack of compliance with cGMP, violations of the Foreign Corrupt Practices Act, and sales of defective products.[6]

On April 22, 2010, the Board appointed a Special Committee to investigate, review and analyze the allegations made in the Demand Letters, and to recommend to the Board what actions, if any, should be taken. On June 15, 2010, in response to additional Demand Letters and the allegations in the Demand Futile Actions, the Board expanded the authority of the Special Committee to investigate, review, and analyze the additional allegations made. On June 27, 2011, the Special Committee issued a report recommending that the Board not pursue litigation on behalf of J&J against any J&J executive or Board member. ECF No. 149, at 120-21. The Board adopted the Special Committee recommendations on July 18, 2011.

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[5] *See Wolin v. Weldon et al.*, No. C-188-10 (Sup. Ct. N.J.), alleging essentially identical claims as *In re Johnson & Johnson Derivative Litigation*; and *Clark v. Coleman et al.*, No. C-116-11 (Sup. Ct. N.J.) and *King v. Coleman et al.,* No. C-159-11 (Sup. Ct. N.J.) (consolidated under *In re Johnson & Johnson Shareholder Derivative Litigation*, No. C-116-11 (Sup. Ct. N.J.)), alleging substantially identical claims as *In re Johnson & Johnson FCPA Shareholder Derivative Litigation*.

[6] The following shareholders made demands upon the J&J Board from February through November 2010: Leslie Katz, Jeffrey Tarson, and Joan Tarson (February 17, 2010 and July 7, 2010); the New Jersey Building Laborers Annuity & New Jersey Building Laborers Pension Funds (March 23, 2010); Glenn Bassett (April 15, 2010); Howard Lipschutz (May 11, 2010);

On August 29, 2011, two shareholders who previously had served Demand Letters filed derivative complaints in this Court, alleging that the Board had wrongfully refused the Demand Letters (the "Demand Refused Actions").[7] Following a motion for consolidation and appointment of lead counsel, the Court consolidated the Demand Refused Actions under Case No. 11-04993, and named Abraham, Fruchter, & Twersky, LLP as Lead Counsel and Kantrowitz, Goldhamer & Graifman, P.C. as Liaison Counsel for the Demand Refused Actions by Order dated November 21, 2011. Pursuant to the settlement discussions, the parties have agreed to extend the dates for the Defendants to answer or otherwise respond to the Demand Refused Actions.

C. The Settlement Process

Shortly before the oral argument on the motion to dismiss the Consolidated Amended Complaint filed in the Demand Futile Actions, Plaintiffs' Counsel and Defendants' Counsel commenced settlement negotiations. Lead Demand Futile Counsel engaged governance and compliance and pharmaceutical experts to assist in formulating corporate governance, health care compliance, and quality control reforms. Specifically, Demand Futile Counsel engaged Harvey Pitt to provide guidance on crafting corporate governance, and Dr. Mitchell Glass to provide guidance on executive quality control and compliance issues.

Working with their experts, Lead Demand Futile Counsel designed and, beginning by letter dated August 31, 2011, presented a series of detailed settlement proposals directed at both the Board and management levels. The Company carefully reviewed these proposals and

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Martha Copeland (May 20, 2010); Dan Miran (May 26, 2010); S.L. Lerner (June 17, 2010); and Michael Waber (Nov. 12, 2010).

[7] *See Copeland v. Prince et al.*, No. 11-04993 (D.N.J.) and *Katz v. Weldon et al.*, No. 11-04994 (D.N.J.).

negotiated extensively with Lead Demand Futile Counsel for seven months and thereafter with respect to them.

Lead Demand Refused Counsel also engaged pharmaceutical and medical device consultants to propose corporate governance, health care compliance, and quality control reforms. Working with their experts, Demand Refused Counsel designed and presented settlement proposals directed at both the Board and management levels. The Company carefully reviewed these proposals and requests, and negotiated with Lead Demand Refused Counsel with respect to them.

The Settling Parties engaged in dialogue regarding relevant policies and procedures in place at the Company, and how the Company could effectively achieve the goals of the proposed reforms. This dialogue included numerous face-to-face meetings among counsel, including in-house counsel for J&J, as well as with Plaintiffs' pharmaceutical consultants and J&J's Chief Quality Officer. The Parties negotiated extensively as well in teleconferences and through the exchange of multiple drafts of the proposed settlement terms.

During the course of the settlement process, the Company made a series of productions of documents relevant to corporate governance and the compliance structure and policies within the J&J organization, including improvements that have been implemented by the Company during the pendency of the Derivative Actions. These documents were reviewed in detail by Lead Demand Futile Counsel and Demand Refused Counsel and their experts, and assisted in the negotiation of the settlement terms.

Lead Demand Futile Counsel and Lead Demand Refused Counsel conducted a thorough investigation into the underlying facts and merits of the Derivative Actions. This investigation began in advance of serving the Derivative Actions and Demand Letters, and continued, with the

assistance of their experts, through to the settlement of the Derivative Actions. The investigation included (i) independent factual and legal analysis, (ii) review of publicly available information including news reports, securities' analyst reports and J&J public filings with the Securities and Exchange Commission ("SEC"), (iii) consultation with their experts, (iv) the review and evaluation of the Special Committee findings, (v) the review of the documents produced by the Company pursuant to the settlement process, as described above, (vi) review of court filings, including trial transcripts and exhibits from other related actions; and (vii) discussions with Company representatives. Plaintiffs' Counsel's investigation was integral to their assessment of the claims and their conclusion that the terms and conditions of this Stipulation and Exhibits A and B confer substantial benefits upon, and are in the best interests of, the Company and its shareholders.

III. PRELIMINARY RELIEF SOUGHT AT THIS TIME

Plaintiffs respectfully request that the Court enter the [Proposed] Order Preliminarily Approving Proposed Settlement, Directing the Issuance of Notice, and Setting a Final Settlement Hearing (the "Preliminary Approval Order"), in the manner and form submitted herein as Exhibit C to the Stipulation. The Preliminary Approval Order, if approved by the Court, will:

(a) preliminarily approve the proposed settlement as set forth in the Stipulation;

(b) establish a procedure for J&J Shareholders to follow should they wish to object to the proposed settlement, including setting a date by which any such objections must be made;

(c) direct that J&J file a Form 8-K (with exhibits) with the SEC, and post settlement-related documents as identified at ¶ 1.26 of the Stipulation on the J&J corporate website, mail the Notice of Proposed Settlement of Derivative Actions, Final Settlement Hearing, and Right to Appear (the "Notice"), substantially in the form attached as Exhibit D to the Stipulation, to the last known address of J&J shareholders of record as of July 10, 2012, and publish the Summary Notice of Proposed Settlement of Johnson & Johnson Shareholder Derivative Actions, Final Settlement Hearing, and Right to Appear (the "Summary Notice"), substantially

in the form attached as Exhibit E to the Stipulation, in accordance with the terms of the Stipulation; and,

(d) schedule a hearing for the Court to consider final approval of the settlement (the "Settlement Hearing").

Plaintiffs, after conferring with Defense Counsel, offer for the Court's consideration the following proposed schedule of dates for the various events leading up to and including the Settlement Hearing:

Filing of the Form 8-K, posting required settlement-related documents on J&J company website and mailing Notice to registered J&J shareholders	within 5 business days of entry of the Preliminary Approval Order
Publication of Summary Notice	within 10 days of entry of the Preliminary Approval Order
Filing of initial brief in support of final approval of settlement	28 days prior to the Settlement Hearing
Last day for Shareholders to file any objection to the settlement	14 days prior to the Settlement Hearing
Filing of supplemental briefs in support of final approval of settlement, as necessary	Up to 7 days prior to the Settlement Hearing
Settlement Hearing	Approximately 60 days following the entry of the Preliminary Approval Order

IV. THE PROPOSED SETTLEMENT MERITS PRELIMINARY APPROVAL

The proposed settlement creates significant benefits for J&J, is the result of intense and protracted arm's-length negotiations between experienced counsel, and merits preliminary approval. *See, e.g.*, Stipulation at ¶¶ R and 8.3. If finally approved by the Court, Plaintiffs will voluntarily dismiss with prejudice their claims against Defendants in return for the significant corporate governance changes achieved for the benefit of J&J and its shareholders.

A. The Preliminary Approval Standard

Plaintiffs filed this action pursuant to Rule 23.1, which provides that "[a] derivative action may be settled, voluntarily dismissed, or compromised only with the court's approval." Fed. R. Civ. P. 23.1(c). The "general practice" in shareholder derivative suits is that the parties

submit the settlement to the Court for its approval together with a request for a hearing on its propriety. *See* 7C CHARLES ALAN WRIGHT, ARTHUR R.MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE: CIVIL 3D § 1839, at 199 (2007). In determining the standards applicable to approval of a derivative settlement, "cases involving dismissal or compromise under Rule 23(e) of nonderivative class actions . . . are relevant by analogy." *Id*., at 195. Moreover, there is an overriding public interest in settling and quieting litigation, in particular derivative, class actions and other complex litigation. *See, e.g., In Re: Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 535 (3d Cir. 2004) ("there is an overriding public interest in settling class action litigation, and it should therefore be encouraged"); *In Re: GMC Pick- up Truck Fuel Tank Prods. Liab. Litig.*, 55 F.3d 768, 784 (3d Cir. 1995) ("the law favors settlement, particularly in class actions and other complex cases where substantial judicial resources can be conserved by avoiding formal litigation"); *In re School Asbestos Litigation*, 921 F.2d 1330, 1333 (3d Cir. 1990) (noting that the court encourages settlement of complex litigation "that otherwise could linger for years").

The Court is not required on preliminary approval to make a final determination that the proposed settlement is fair and reasonable. "If the preliminary evaluation of the proposed settlement does not disclose grounds to doubt its fairness or other obvious deficiencies . . . and appears to fall within the range of possible approval," the Court should direct that notice be disseminated and schedule a final approval hearing. *Manual for Complex Litigation Third* §30.41 at 297 (the "Manual"). "In evaluating a settlement for preliminary approval, the court determines whether the proposed settlement discloses grounds to doubt its fairness or other obvious deficiencies such as unduly preferential treatment of class representatives or segments of the class, or excessive compensation of attorneys, and whether it appears to fall within the range

of possible approval." *Tenuto v. Transworld Sys.*, No. Civ. A. 99-4228, 2001 U. S. Dist. LEXIS 17694, at *3 (E.D. Pa. Oct. 31, 2001). In this regard, the Third Circuit has held that the principal factor in determining the fairness of a derivative settlement is "the extent of the benefit to be derived from the proposed settlement by the corporation, the real party in interest." *Shlensky v. Dorsey*, 574 F.2d 131, 147 (3d Cir. 1978). Further, courts have long recognized that in derivative actions, non-monetary benefits, such as material changes in corporate management or policies, provide real and substantial benefits and warrant approval. The Courts' recognition of the importance of these types of reforms has heightened in the post-Enron era. *See, e.g.*, *Unite Nat'l Ret. Fund v. Watts*, 2005 U.S. Dist. LEXIS 26246 *9-*10 (D.N.J. Oct. 28, 2005) ("*Shell Deriv.*") (approving governance and compliance relief, noting that "the most important factor in evaluating the fairness of the settlement agreement is the benefit to the corporation").

B. The Proposed Settlement Presents No Grounds to Doubt its Fairness

In assessing at the preliminary approval stage whether a proposed settlement raises any issue as to fairness, courts often focus on whether the settlement is the product of arm's-length negotiations. *See, e.g., In re Automotive Refinishing Paint Antitrust Litigation*, 2006 U.S. Dist. LEXIS 93936 (E. D. Pa. 2006) (citing *In re Prudential Sec. Inc. Ltd. P'ship Litig.*, 163 F.R.D. 200, 209 (S.D.N.Y.1995)); *Tenuto*, 2001 U. S. Dist. LEXIS 17694, at *3 ("The settlement agreement is a product of lengthy arm's-length negotiations, concluded after completion of discovery.").

Prior to arriving at the proposed settlement in this case, Plaintiffs' Counsel conducted a detailed, independent factual investigation and legal analysis in connection with the Derivative Actions. This included review of publicly available information including news reports, securities' analyst reports, J&J's public filings and court records; close coordination with

pharmaceutical and corporate governance experts; extensive legal research and analysis supporting the legal merits of their fiduciary duty claims; and analysis of the scope and nature of resultant derivative damages Plaintiffs contend that J&J incurred. In addition, Plaintiffs' Counsel reviewed and analyzed with their experts relevant internal documents produced by the Company pursuant to the settlement process.

In addition, the negotiation process here was undertaken at arm's-length, was intensive and was hard fought. As discussed above, settlement negotiations in this case occurred over a lengthy period, and included the exchange of multiple proposals, designed by Plaintiffs' Counsel working in close coordination with their pharmaceutical and their governance and compliance experts. The negotiation process included both face-to-face meetings and telephone conferences among, at various times, Plaintiffs' Counsel, Defendants' Counsel, in-house J&J counsel, Plaintiffs' pharmaceutical experts and J&J's CQO. The terms and conditions of the Stipulation, and Exhibits A and B are the results of this intensive, arm's-length process. *See, e.g.*, *Cohn v. Nelson*, 375 F. Supp. 2d 844, 855 (E.D. Mo. 2005) ("In assessing the merits of the settlement, plaintiffs' counsel considered the factual and legal questions that were disputed in the derivative actions. The court considered that the proposed settlement was made after counsel had conducted an extensive investigation ... ."). There are no grounds to doubt the fairness of the proposed settlement or the intensive, arm's-length negotiations that achieved it.

C. The Proposed Settlement Provides Substantial Benefits to J&J and its Shareholders

As noted above, the Third Circuit has found that the principal factor in determining the fairness of a derivative settlement is "the extent of the benefit to be derived from the proposed settlement by the corporation, the real party in interest." *Shlensky*, 574 F.2d at 147. The proposed settlement here provides substantial benefits to J&J and its shareholders. As discussed

below, at the heart of the proposed settlement is J&J's agreement to adopt governance reforms that will support the early identification, upward reporting, prevention and timely resolution of noncompliance with drug marketing laws, cGMP regulations and internal policies, procedures and standards. These reforms, from the adoption and implementation during 2013 of the Product Risk Management Standard, through the adoption of robust and detailed reporting to the newly formed Regulatory, Compliance and Government Affairs Committee of the Board (the "RCGC'), go to the heart of Plaintiffs' allegations underlying the Derivative Actions. Plaintiffs believe a fundamental defect in J&J's prior approach to compliance and quality control was its use of a decentralized model for internal reporting and oversight, leading to a lack of ownership and accountability. If implemented with fidelity, Plaintiffs believe that the proposed settlement will place J&J at the forefront of best practices in the industry, and provide substantial benefits to the Company and its shareholders in the early detection and prevention of enterprise-wide product issues. Key aspects of the proposed settlement include:

1. J&J's Adoption of the Quality and Compliance ("Q&C") Core Objective

Under the terms of the proposed settlement, the J&J Board, by resolution, will adopt the new Q&C Core Objective, pursuant to which the Company will affirm its resolve to operate its businesses, sectors, entities and franchises in compliance with applicable laws, regulations and J&J policies and standards, to deliver high quality products that patients and providers can trust, and to conduct its activities, and have policies and procedures in place so as to minimize adverse regulatory enforcement action. The Q&C Core Objective requires that J&J design and maintain robust quality control and quality assurance systems to prevent, timely detect and correct noncompliance with drug marketing laws, cGMP regulations, and J&J's internal policies, procedures and standards, including the new PRM Standard (described below). To ensure

problems and issues are not permitted to remain unresolved at the operational company level, the Q&C Core Objective requires that these control and quality assurance systems will include tracking remediation against established timelines, and that these systems must be subject to benchmarks and metrics. *See* Exhibit A, Section I.

The implementation of PRM in particular, and the central tenets of early identification and tracking across the range of product and compliance issues at the highest reaches of the Company required under the Q&C Core Objective, are significant in the message they send throughout the enterprise, to J&J's shareholders and other constituents. The Board's adoption of the Q&C Core Objective reflects the Board's recognition of its own obligations and oversight responsibilities with respect to compliance throughout the entire life cycle of J&J products, including as related to marketing and promotion of drugs and devices, and of its oversight responsibility in connection with the expanding role of independent compliance and quality functions at the Company, including oversight of resource allocations to these critical functions.

2. Making Adherence to the Quality and Compliance Core Objective a Factor in the Evaluation and Compensation of All J&J Employees

The settlement requires that the Q&C Core Objective will be disseminated in a Company-wide communication, with similar communications being disseminated enterprise-wide on an annual basis thereafter. *See* Exhibit A, Section II. Moreover, these communications will instruct that adherence to and furtherance of the Q&C Core Objective will be considered in the evaluation and compensation of J&J's 120,000 employees, including J&J's senior management. Plaintiffs believe that this last requirement is of particular importance. One of the most effective ways to ensure directives from the top are embraced and adhered to below is to tie individual employee compensation to compliance with such directives, and to tie the compensation of management to the successful implementation of such directives throughout

their functional areas of responsibility. The new Charter of the Regulatory Compliance Committee (discussed below) will further help to ensure the effective implementation of this requirement by providing that the RCGC must also "consult with the Compensation and Benefits Committee of the Board regarding the application of the Quality and Compliance Core Objective in employee performance evaluations and compensation." Charter, "Duties and Responsibilities of the Committee," ¶ 12.

3. Adoption of the RCGC Charter and Operating Procedure

J&J has agreed that the RCGC will operate in accordance with the Charter and the Operating Procedure (the "C/OP") set forth at Exhibit A, Section III., A. and B. The C/OP ensures that the RCGC assumes oversight responsibility over all aspects of non-financial quality control and regulatory compliance at J&J, including the Company's compliance with drug marketing laws and cGMP regulations. To ensure that the RCGC is armed with sufficient information to carry out its functions and responsibilities, the C/OP requires that the Committee receive robust and regular reporting from relevant management areas at the Company, including quarterly compliance updates from the J&J Chief Compliance Officer ("CCO"), the J&J Chief Quality Officer ("CQO"), and the Vice President Corporate Internal Audit ("V.P. CIA"), to support and track the effective implementation and operation of regulatory compliance and compliance and quality programs and systems at J&J. This reporting regarding the implementation and effectiveness of quality programs will include CQO reporting regarding the implementation and effectiveness of the PRM Standard at the Company. The C/OP places responsibility in the RCGC to oversee the adequacy of funding of the compliance and quality functions, thereby providing a critical safeguard against the pressure to underfund these areas. *See* Charter, "Duties and Responsibilities of the Committee," ¶¶ 3, 4. The C/OP also places responsibility on the RCGC itself to assess the adequacy of the information it is receiving to

support its oversight functions set forth in the C/OP. *See* Charter, "Oversight of Committee Matters," ¶ 3. Combined with their detailed required reporting obligations under the proposed settlement, the Charter and Operating Procedure provide that the CCO, CQO and V.P. CIA will have direct access to the Committee and its Chairman (Operating Procedure, ¶ 6), and that the RCGC will hold separate private meetings at least semi-annually with these officers, among others. Charter, "Meetings of the Committee," ¶ 2. Recognizing that issues may arise that require reporting to the RCGC even more promptly than on a quarterly basis, the settlement provides for interim reporting directly to the RCGC Chair. *See* Operating Procedure, ¶ 3.a., b., c. and d.

In addition to the reporting with respect to the implementation and operation of the key compliance and quality systems, including PRM, the Operating Procedure requires the CCO, CQO and V.P. Supply Chain each independently to report on trends affecting the Company in his or her respective area, and, "as appropriate, plans of action to respond to such trends from a preventive standpoint." *See* Operating Procedure, ¶¶ 3. a., b. and d. In addition, the Charter provides that the RCGC shall oversee the Company's exposure to risk relating to regulatory compliance, Health Care Compliance & Privacy and Quality & Compliance matters, and shall review and evaluate new developments and current and emerging trends relating to regulatory compliance, quality and government relations that affect or could affect the Company. *See* Charter, "Duties and Responsibilities of the Committee," ¶¶ 10 and 13. By directly addressing regulatory and risk-related trends as they first develop or arise, Plaintiffs believe that J&J will be better positioned to act proactively to avoid problems and issues which those trends may signal going forward. The Operating Procedure also requires the RCGC at least biennially to consider the effectiveness of, and recommend changes to, J&J's enterprise risk management ("ERM")

program for those ERM areas under the Committee's purview, and to report any recommended changes to the full Board. *See* Operating Procedure, ¶ 4.

4. Adoption of the Product Risk Management Standard

The proposed settlement requires J&J to design and implement a Product Risk Management ("PRM") Standard under the Quality Policy and Quality Framework. The PRM Standard will be a mandatory standard applicable across the J&J enterprise. Responsibility for the design and implementation of the PRM Standard will rest with the CQO and the J&J Quality organization. The PRM Standard will address, among other things, the requirement to develop resolution timelines and action plans, and quality metrics for evaluating issue resolution, including tracking remediation of issues against established timelines. The CQO also will be responsible for ensuring the design and adoption of appropriate implementing sector standards and SOPs. Responsibility for oversight of compliance with the PRM Standard will rest with the independent Enterprise Regulatory Compliance Group and the J&J Quality organization. The CQO will provide reporting to the RCGC on the implementation and effectiveness of the PRM Standard in accordance with the C/OP. Plaintiffs believe this critical responsibility, vested with the CQO and the independent Quality organization, will provide important safeguards against any commercial pressures that may be brought to bear in the identification and timely resolution of product issues at J&J.

Plaintiffs believe that the PRM Standard will provide for the effective identification of product issues at the level of the product team (or its equivalent) at J&J operating companies enterprise-wide, which will address Plaintiffs' concern that issues lingered at J&J subsidiaries for too long. The PRM Standard will also address the escalation process for issues arising with products, including up the Quality organization as appropriate. Quality personnel will apply quality metrics to evaluate issue resolution, including whether identified issues are being

remediated in accordance with established timelines. In addition, the implementation of the PRM Standard will result in the active sharing of best practices with respect to product risk management across J&J. Plaintiffs believe that the PRM Standard, once implemented across J&J, will effectively ensure the early identification, timely remediation and accountability for resolution of product issues at the Company.

Critically, Defendants have agreed to implement the new PRM standard in 2013. This undertaking, across the enterprise, will require leadership at the highest levels of the Company and a significant commitment of financial resources.

5. New Adverse Event Management and Non-Conformance Management Standards

The proposed settlement provides that J&J will design and implement both an Enterprise-wide Adverse Event Management ("AE") Standard and a Non-Conformance Management ("NC") Standard under the Quality Policy and the Quality Framework. The AE Standard will enhance existing AE standards, and will address the process for health authority reporting of undesirable experiences associated with the use of regulated J&J products. The NC Standard will address the process for documenting and processing non-conformances in manufacturing or distribution in order to control and prevent the release of J&J products that do not conform to specified requirements. Both the AE and NC Standards will be implemented prior to or during 2014.

6. Settlement Commitment Term and Funding Provisions

The Company has agreed to maintain the provisions of the settlement as set forth in Exhibits A and B, for a period of not less than five years from the Effective Date of the Settlement. *See* Stipulation, ¶ 2.3. Five years is a substantial period of time to permit these reforms to become part of the J&J culture going forward.

The Company has agreed that for the Settlement Commitment Term it will spend such funds as are necessary to implement and maintain the Exhibit A and B provisions, and that the CQO or CCO have discretion to make funding recommendations directly to the Board or an appropriate committee of the Board. *Id.*, ¶ 2.2. The ability of the CQO and the CCO to directly seek Board intervention in funding determinations significantly strengthens their ability to ensure the streams of funding necessary to fully implement these reforms.

* * *

Plaintiffs respectfully submit that the proposed settlement clearly benefits J&J and therefore clearly falls "within the range of possible approval." *See Shell Deriv.*, 2005 U.S. Dist. LEXIS 26246 *18 ("the great benefit conferred upon Shell as a result of the new corporate governance principles provided for in the settlement agreement . . . will serve to prevent and protect Shell from the reoccurrence of certain alleged wrongdoings."); *In re Schering-Plough Corp. Shareholder Derivative Litig.,* 2008 U.S. Dist. LEXIS 2569 at *3-4 (D.N.J. 2008) (approving settlement "seek[ing] to foster the active involvement of the Board in oversight" and resulting in "the Board's oversight function [being] strengthened").

The Court should grant preliminary approval to the proposed settlement.

V. THE PROPOSED NOTICE TO J&J SHAREHOLDERS IS ADEQUATE

If the Court grants preliminary approval, J&J will notify the current J&J shareholders pursuant to the Preliminary Approval Order of the Settlement by (1) filing a Form 8-K regarding the proposed settlement, which shall include as attachments a copy of the Notice of the Proposed Settlement (substantially in the form attached hereto as Exhibit D), the Stipulation of Settlement, and Exhibits A and B (with exhibits, the "Form 8-K"); (2) posting on J&J's corporate website copies of the Stipulation of Settlement, Exhibits A and B and the Notice of the Proposed Settlement; (3) publishing the Summary Notice of the Proposed Settlement (substantially in the

form attached hereto as Exhibit E), once each in the national edition of *The Wall Street Journal* and *USA Today* and over *PR Newswire*; and (4) mailing the Notice of the Proposed Settlement to those shareholders who are registered shareholders of J&J as of the date the Stipulation was signed.

The proposed forms of notice will fairly and reasonably apprise J&J shareholders of the essential terms of the proposed settlement and of information regarding Plaintiffs' Counsel's fee application. It will also set forth the procedure for objecting to the settlement or to the request for an award of attorneys' fees and reimbursement of expenses. Thus, the proposed forms of notice fully satisfy due process requirements. *See Bell Atlantic Corp. v. Bolger*, 2 F.3d 1304, 1317 (3d Cir. 1993) (notice held adequate because it "summarized the Bell of Pennsylvania matter, the procedural history, the parties' contentions, the issues involved, the reasons each party recommended settlement, and the terms of the settlement agreement" and it "advised shareholders of their right to object, the consequences of not doing so, and how to go about obtaining further information available on file with the court") (citing *Kyriazi v. Western Elec. Co.*, 647 F.2d 388, 395 (3d Cir.1981)); *In re Corel Corp. Sec. Litig.*, 293 F. Supp. 2d 484, 2003 U.S. Dist. LEXIS 21024 (E.D. Pa. 2003).

VI. CONCLUSION

Plaintiffs respectfully request that the form of [Proposed] Preliminary Approval Order (Exhibit C to the Stipulation), be entered granting preliminary approval to the proposed settlement, setting a date for the Settlement Hearing and ordering notice to J&J shareholders as described above to be disseminated in the manner as provided in the Stipulation.

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Co-Lead Counsel for Plaintiffs

By: */s/James E. Cecchi*
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Dated: July 11, 2012

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